

Remarks

The Rejection of Claims 3, 11, 14, 24, 35, and 58 Under 35 U.S.C. § 112 ¶ 1

Claims 3, 11, 14, 24, 35, and 58 stand rejected under 35 U.S.C. § 112 ¶ 1 as insufficiently described because “[t]he term ‘data storage medium’ does not appear to be recited anywhere in the instant specification.” Final Office Action at page 4, last paragraph. Applicants respectfully traverse the rejection.

It is well known that a specification need not set forth an invention in *ipsis verbis* in order to satisfy the written description requirement. *In re Lukach*, 442 F.2d 967, 969, 160 U.S.P.Q. 795, 796 (C.C.P.A. 1971). The members of the Markush group recited in claims 3, 11, 14, 24, 35, and 58 are all disclosed in the specification and are all data storage media.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 52-64 Under 35 U.S.C. § 112 ¶ 2

Claims 52-64 stand rejected under 35 U.S.C. § 112 ¶ 2. Applicants respectfully traverse the rejection.

Claims 52-58 allegedly omit an essential step of comparing hepsin gene copy number in a control group to that in a test group. To advance prosecution, independent claim 52 is amended to recite “amplification of the hepsin gene copy number relative to a control hepsin gene copy number.” This amendment expressly complies with a requirement set forth in the Final Office Action.

The recitations “first indirect measure” and “second indirect measure” in claims 59-64 allegedly are indefinite. Under the second paragraph of 35 U.S.C. § 112, the relevant inquiry

. . . is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

In re Moore, 439 F.2d 1232, 1235, 58 C.C.P.A. 1042, 1046-47 (1971) (footnote omitted). One of ordinary skill in the art would understand that, in the context of determining gene copy number, any method other than directly counting copies of genes is, by definition, an indirect measure of gene copy number. Indirect methods of detecting gene copy number were well known in the art when this application was filed. As the specification teaches, these methods include Southern blotting, *in situ* hybridization, comparative genomic hybridization (CGH), amplification-based assays (e.g., a PCR-based TaqMan assay), and DNA microarray-based CGH (pages 41-43; Example 1). Each of these methods detects a measurement which reflects gene copy number and is, therefore, indirect. In the context of the specification and the knowledge of one of ordinary skill, the term "indirect measure" as used in claims 59-64 is definite.

Under 35 U.S.C. § 112, second paragraph, the claims must "reasonably apprise those skilled in the art both of the utilization and scope of the invention." *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136, 118 U.S.P.Q. 122, 130 (2d Cir. 1958), *cert. denied*, 358 U.S. 884 (1958). Claims 52-64 serve this purpose. Claims 52-64 are therefore definite.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: February 14, 2006

By: *Lisa M. Hemmendinger*
Lisa M. Hemmendinger
Registration No. 42,653

Customer No. 22907